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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

GARBER, CHARLES D

ART UNIT	PAPER NUMBER
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2856

DATE MAILED: 06/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/085,687

Applicant(s)

MEHRA ET AL.

Examiner

Charles Garber

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) 20-34, 41-52, 54 and 55 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 35-40 and 53 is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 February 2002 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group II in Paper No. 6 is acknowledged.

The traversal is on the ground(s) that the searches overlap as evidenced by there being linking claims and common class and subclass at least between Groups II and III and because there is no undue burden on the Examiner. This is not found persuasive because though the searches may in fact overlap, the searches are distinct and not confined to the single class and subclass cited by the Examiner. The searches would in fact include many other classes and subclasses based upon the particular limitations unique to each invention Examiner has determined. Searching all the limitations of the various inventions therefore will be a significant and undue burden upon the Examiner.

The requirement is still deemed proper and is therefore made FINAL.

Drawings

The drawings are objected to because figures 4a and 4b are identical, one of the figures is either incorrect or not required. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-6, 10, 13 -16 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith (US Patent 6,117,394).

Regarding claim 1, Smith discloses a membrane filtered pipette tip used in nucleotide sequence analysis (title and background) which is equivalent to a device for removing an aliquot or portion of biological sample. Figures 2, 3D, 4, 10C and 11C show sample being taken or aspirated from receptacle. In addition, needle 30 is provided for cases when a surface must be pierced in order to take a sample which is equivalent to removing samples from a sealed receptacle as in the instant invention.

Figures 10C, 11C and 12 illustrate a multiple pipette tip with attached well for precision volume multiple pipetting and are shown having inner and outer walls and top and bottom ends forming a hollow chamber. "These tips are designed to hold a particular pre-calculated volume" thus defining a predefined volume as in the instant invention.

Needle 30 shown in an optional embodiment is shown in figure 4B with a hollow piercing tip and blunt end wherein the blunt end is engaged to the bottom end of the hollow chamber. The piercing end may be sharp. (column 7 line 61 to column 8 line 2)

Smith also includes a membrane filter M shown in figure 2 contacting the inside wall of the hollow pipette. (column 4 lines 65+)

Claim 10 is substantively equivalent to claim 1 as discussed above except for the express intended use of the filter barrier for preventing cross-contamination of fluids, aerosols, or samples beyond said hollow chamber. However, the reference recites "tips having a first filter for filtering material drawn into the pipette tip and second filters from preventing contamination of the pipette." (abstract) The specific placement of the filter (similar to that of the instant invention as illustrated in the specification figures) will inherently prevent contamination beyond the hollow chamber as in the instant invention.

As for claims 4 and 13, figures 2, 3D, 4, 10C and 11C show sample being taken from a tube like receptacle.

As for claim 14, Smith further discloses that the "concept can be incorporated into any of the proposed tip configurations and would be especially beneficial in the multichannel pipetters and useful in automated pipetting machinery...."

As for claims 5 and 15, the pipette tips T and/or the piercing tip 30 is inherently disposable.

As for claims 6 and 16, Smith further discloses the filter may be hydrophobic allowing only sterile gases to pass (column 5 lines 35-40) and the filters may be made from Nitrocellulose, Cellulose Acetate, Nylon, PTFE, etc.) and are autoclavable, hydrophobic, gamma irradiation sterilable. (column 4 lines 40-60)

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith (US Patent 6,117,394) in view of Preston et al. (US Patent 6,274,087).

Smith as discussed above with respect to claims 1 and 10 lack the piercing tip retractable within the hollow chamber.

Preston teaches needle 20 retractable within a hollow chamber as shown in figures 8A and 9A. The needle only extends when a sample vial is within a holder. (column 2 lines 1-9)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide for a retractable and extensible needle in a sampling device so that an operator may not be inadvertently pricked.

Claims 3, 7-9, 12 and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith (US Patent 6,117,394)

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Regarding claims 3 and 12, Smith as discussed above does not expressly recite what types of intended biological samples may be used with the device and therefore may be used with any type of biological sample. However Examiner considers that it is widely known that any type of biological sample may include blood, plasma, spinal fluid, serum, saliva, sputum, urine, feces, Buccal cells, spermatozoa, solid tissue, bacteria, yeast, viral samples, semen, cultured cells lines, plants, and combinations thereof as in the instant invention.

One having ordinary skill in the art would have known of the advantage of sampling for purposes of analysis any material obtained from a living source (e.g. human, animal, plant, bacteria, fungi, protist, virus). One of ordinary skill would also have known the biological sample can be in any form, including solid materials (e.g. tissue, cell pellets and biopsies) and biological fluids (e.g. urine, blood, saliva, amniotic fluid, seminal fluid and mouth wash (containing buccal cells)). Medical and pharmacological analysis and experimentation involves examination of all types of living material.

As for claim 7 and 17, Smith discloses drawing samples sized from 0.5 to 50 microliter and lacks drawing larger samples in the additional range from 51 microliter to 50,000 microliters as in the instant invention. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to samples from 51 microliter to 50,000 microliters, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. In this case, the

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general conditions defining a pipette tip with a filter are satisfied by Smith. The instant invention does not provide any novel or non-obvious structure related to achieving a specific volume range in sampling. In fact, the difficulty in the state of the art appears to be related to achieving the very smallest of sample sizes and not the larger.

As for claims 8 and 18, Smith discloses drawing samples sized from 0.5 to 50 microliter and lacks drawing larger samples in the additional range from 51 microliter to 1,000 microliters as in the instant invention. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to samples from 51 microliter to 1,000 microliters, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. In this case, the general conditions defining a pipette tip with a filter are satisfied by Smith. The instant invention does not provide any novel or non-obvious structure related to achieving a specific volume range in sampling. In fact, the difficulty in the state of the art appears to be related to achieving the very smallest of sample sizes and not the larger.

As for claims 9 and 19, Smith discloses drawing samples sized from 0.5 to 50 microliter and lacks drawing larger samples in the additional range from 51 microliter to 100 microliters as in the instant invention. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to samples from 51 microliter to 100 microliters, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. In this case, the

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general conditions defining a pipette tip with a filter are satisfied by Smith. The instant invention does not provide any novel or non-obvious structure related to achieving a specific volume range in sampling. In fact, the difficulty in the state of the art appears to be related to achieving the very smallest of sample sizes and not the larger.

Allowable Subject Matter

Claims 35-40 and 53 are allowed.

Regarding claim 35, the prior art discussed above teaches all the limitations as in the instant invention except for a side vent positioned within the hollow chamber and between the filter barrier and piercing tip; and a deflector plate separating the hollow chamber and the side vent; wherein the deflector plate substantially prevents or blocks excess sample from entering into the side vent.

While venting of sample chambers is considered well known in the art the use of deflectors or baffles is less well known and the combination of the two is absent in the art of record. The closest prior art of Villa-Real (US Patent 4,492,634) teaches a baffle 8A used to curtail hemolysis of blood. However, the prior art of sampling devices does not teach a baffle separating a hollow chamber and side vent as in the instant invention.

Claims 36-40 depending from allowable claim 35 are allowable for the same reason.

Claim 53 is substantively equivalent to claim 35 is allowable for the same reason.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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The additional references cited on the accompanying form PTO-892 though not cited above are provided to indicate other prior art sampling devices and methods which include one or more features or limitations in common with the instant invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles Garber whose telephone number is (703) 308-6062. The examiner can normally be reached on 6:30 a.m. to 3:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron Williams can be reached on (703) 305-4705. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7725 for regular communications and (703) 308-7725 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-4900.

A handwritten signature in black ink, appearing to read 'CDG', is positioned in the center of the page.

cdg
June 2, 2003